Blood Bank
of San Bernardino
and Riverside Counties

September 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket 98N-0581
Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents
Proposed rule

To Whom It May Concern:

I have read the above mentioned proposed regulations and would like to offer the following comments.

1. REQUIREMENT TO TEST ALL AUTOLOGOUS UNITS

This proposal makes a great deal of sense for the reasons the agency outlines so clearly: errors and accidents in the transfusion of autologous blood occur with sufficient frequency to compromise the safety of both autologous and allogeneic transfusion; breakage of autologous units during laboratory processing or product transport exposes health care staff to viruses; and clerical errors in inventory management including inadvertent crossover may (and do) occur. However, all the safety gained from testing is lost if the units are released after a positive test for HIV, HBsAg or HCV is discovered. I do NOT believe that any changes in the labeling will reduce the probability of any of these occurrences. Certainly it cannot change the likelihood of a unit breaking in a centrifuge or during transport. Likewise, when a unit is inadvertently crossed over to another patient, it is not generally because of the labeling. It is because the nurse misidentified the patient. Autologous units are clearly labeled today, and yet the errors continue to occur, as was pointed out by the agency. Contrary to the manner in which some have interpreted a Supreme Court decision, I believe that release of these units compromises the safety of other patients and health care workers. The agency's conclusion that testing would reduce any risk to the public health posed by the inadvertent improper use of potentially infectious products is incorrect. Only the quick disposal of HCV, HBV and HIV infectious units, and a policy not to continue to draw more units from infectious patients, can reduce the risk.

In its analysis of the impact of testing autologous donations, the agency cites the reduction in risk that occurred when testing for HIV, HBV and HCV was implemented. These reductions occurred not because the units were tested, but because the units were DISCARDED, and the donors deferred, when a positive test was found.

In summary, I fail to see how TESTING autologous units will decrease risk. This only works if as a result of testing, the units are discarded and the donors are deferred. It's simply a waste of money to test these units if the units are to be released. My first choice would be to test the units and then discard the HIV, HBsAg and HCV positives. My second choice would be not to test the units if they must be released.

98N-0581

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2. REQUIREMENT FOR SUPPLEMENTAL TESTING OF ALL REPEATEDLY REACTIVE DONATIONS

Hospitals are being inadequately reimbursed for blood transfusions today, and increasing the cost will only make matters worse. These costs are NOT being passed along to patients, Medicare and insurers. (In California, where HMO penetration is high, there is no additional reimbursement by HMOs for blood as costs soar.) Some blood centers may chose to perform supplemental testing in order to counsel donors. However, some tests (HCV supplemental in particular) are very expensive. Blood centers may perform supplemental testing only on those donors who have a prior donation on whom lookback will be performed. This amounts to only 25% of the HCV positive donors at our center. We advise first time donors to see their doctor for more complete testing. Blood centers and hospitals can ill afford to adsorb the additional cost of HCV supplemental testing (a minimum of $150 per donor, not including shipping and handling costs). There is nothing in the financial impact considerations that addresses the increase in cost to blood centers (only plasma centers are included) as a result of this change in regulations.

The logic that such testing is needed for re-entry is not a reason to mandate supplemental testing. If blood centers want to re-enter donors, they are already performing the testing. Certainly nothing, except perhaps the regulatory challenges faced by blood centers, prevents re-entry of donors without this regulation.

Thank you for the opportunity to respond to these issues.

Sincerely,

Pat Distler

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Vice President, Operations

PD:lmr\7207

ADMINISTRATION
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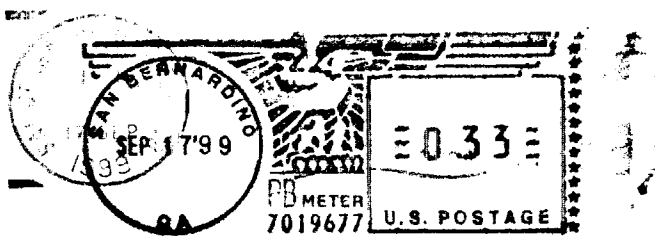

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